UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION	**Civil Action No. 3:16-md-2738-FLW-LHG** **MDL No. 2738**
THIS DOCUMENT RELATES TO ALL CASES	

THE PLAINTIFFS' STEERING COMMITTEE'S MEMORANDUM OF LAW IN RESPONSE AND OPPOSITION TO DEFENDANTS JOHNSON& JOHNSON AND JOHNSON & JOHNSON CONSUMER INC.'S MOTION TO EXCLUDE EXPERT OPINIONS OF GHASSAN SAED

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The Plaintiffs' Steering Committee ("PSC") submits this memorandum of law in opposition to Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc.'s Motion to Exclude Expert Opinions of Ghassan Saed.[1] Faced with compelling, peer-reviewed evidence that it is biologically plausible for their Talcum Powder Products to induce inflammation and alter the redox balance favoring a pro-oxidant state in normal ovarian epithelial cells that can cause ovarian cancer, Defendants attack not only the work, but the reputation and integrity of a respected scientist who has researched and investigated the role of oxidative stress in the pathogenesis of ovarian cancer for nearly 30 years. Defendants' "no-holds-barred" approach and steps taken to discredit Dr. Saed and his work underscore not only the relevance but the significance of his findings to the present litigation.[2]

Whether fueled through ignorance or malicious intent, Defendants project an erroneous picture of the recent research conducted by Dr. Saed and his opinions offered in this litigation, opinions which are grounded not only in his published manuscript, but decades of focus on the issue of oxidative stress in the pathogenesis

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[1] *Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc.'s Memorandum of Law in Support of Motion to Exclude Expert Opinions of Ghassan Saed is referred* to herein as "Defs. Mem. at __."

[2] The baseless assertion of "downright fraud" (Defs. Mem. at 2) exemplifies the lack of professionalism and absence of proper advocacy that has come to be expected from opposing counsel. So too do statements by Defendants that Plaintiffs' counsels' claims of privilege over e-mails exchanged with Dr. Saed infer that counsel was involved in the design, conduct and drafting of the experiments. (Defs. Mem. at 9, fn. 23).

of ovarian cancer. Even Defendants' own experts acknowledge that Dr. Saed is a recognized expert in the field,[3] having authored over 130 peer-reviewed and published studies in his area of expertise.

This Court should see through Defendants' brutal efforts to undermine the work of Dr. Saed and deny the motion to exclude his testimony.

I. BACKGROUND

A. DR. GHASSAN SAED

Dr. Ghassan Saed is an Associate Professor with tenure at Wayne State University where he is the Director of Ovarian Cancer Research.[4] He is a faculty member in the Departments of Obstetrics & Gynecology, Cell Biology, and Anatomy & Physiology at Wayne State School of Medicine, and is a Member of the Karmanos Cancer Institute, Molecular Biology and Genetics Program.[5] As the Director of Ovarian Cancer Research, Dr. Saed's laboratory investigates the role of oxidative stress in the pathogenesis of ovarian cancer. His research in ovarian cancer

[3] *See* March 29, 2019 deposition of Michael Birrer, M.D., Ph.D. ("Birrer Dep.") at 394:1-17; 311:11-312:2 (testifying that authors of review articles in reputable journals are felt to be experts in the field, and that Dr. Saed's research over his career has addressed the role of oxidative stress and gene amplification in gynecological tumors), excerpts of which are attached hereto as **Exhibit A.**

[4] *See* November 16, 2018 Rule 26 Expert Report of Dr. Ghassan M. Saed ("Saed Report") at 2, attached hereto as **Exhibit B.**

[5] *Id.*

has resulted in the identification of biomarkers for assessing the progression and metastasis of ovarian cancer.[6]

Dr. Saed has been the recipient of national, peer-reviewed and international grants and contracts from prestigious organizations and he has been a prolific publisher and presenter at scientific meetings. He has been an author on more than 130 original studies published in peer-reviewed journals in addition to writing review articles and book chapters.[7] Dr. Saed recently published a review article in the journal *Gynecologic Oncology* titled "Updates of the role of oxidative stress in the pathogenesis of ovarian cancer."[8] In addition, as of February 28, 2019, Dr. Saed's research related to talcum powder products, inflammation and oxidative stress has been peer-reviewed and published in *Reproductive Sciences*, a publication of The Society for Reproductive Investigation, that publishes original research and reviews, editorials, and position papers in all aspects of reproductive biology and its translation to clinical medicine, including the discipline of gynecologic/reproductive tract oncology.[9] As Dr. Saed has stated, this is what he has done "for the last 30

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[6] *Id.*

[7] *Id.* at 3.

[8] *Id.*

[9] *See* Fletcher, N., *et al.*, Molecular Basis Supporting the Association of Talcum Powder Use With Increased Risk of Ovarian Cancer, Reprod. Sci., Feb. 2019 (hereinafter "Saed Publication"), attached hereto as **Exhibit C.** *See also* January 23,

years, ovarian cancer, oxidative stress, and inflammation."[10] Dr. Saed's "specialty is anything that induces inflammation and oxidative stress that is linked to ovarian cancer."[11]

As reflected above, in his *curriculum vitae*, and his publication record, Dr. Saed is an established translational researcher, and his research interest currently focuses on the identification of biomarkers for the early detection of ovarian cancer, and the characterization of novel therapeutic targets for the treatment of ovarian cancer. Dr. Saed and his staff would be expected to, and do have the expertise and experience to conduct the experiments that form the basis of his talcum powder research and opinions offered in this case.

B. DR. SAED'S RESEARCH

Dr. Saed was contacted by the PSC in and around August of 2017.[12] Dr. Saed did not have a relationship with the PSC at that time and he was asked about "the possibility of acting as a witness expert in ovarian cancer inflammation and oxidative

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2019 Deposition of Ghassan Saed, Ph.D., Exhibit 12 (Sage Publishing website printout), attached hereto as **Exhibit D.**

[10] *See* January 23, 2019 and February 14, 2019 Depositions of Ghassan Saed, Ph.D. ("Saed Dep.") at 27:4-6, excerpts of which are attached hereto as **Exhibit E.**

[11] *Id.* at 27:10-11; 30:11-13 ("anything that causes inflammation, redox imbalance, is linked to increased risk of ovarian cancer. This is the core of my work.").

[12] *Id.* at 25:2-4.

stress."[13] Dr. Saed agreed in principle "to serve as a consultant for what [he] is an expert in, which is oxidative stress and ovarian cancer, and [he] promised to run data, do some work, because ***[he] wanted to find out if there is molecular evidence to support the effect of talcum powder on the markers [he] stud[ies].***"[14] As Dr. Saed testified, as routinely done in his lab, he "ran a pilot experiment using PCR, using single dose, and when we saw the data and we saw that there's a biological effect, then we had a plan of what to do, and which is the whole study."[15]

1. Dr. Saed's Budget Document

Dr. Saed prepared a budget document entitled "The role of talc powder exposure in ovarian cancer: mechanistic approach" in order to estimate how much the project would cost him if he wanted to do it."[16] The Budget Document was not prepared for anyone other than himself, for his lab. It represented his plan, his thinking.[17] Dr. Saed prepared a budget document because the costs of the experiments would ultimately be borne by his lab. The work done by Dr. Saed on the talc project was not paid for by the PSC. As Dr. Saed explained, his lab is

[13] *Id.* at 25:11-17; 27:3-6.

[14] *Id.* at 276:15-20 (emphasis added).

[15] *Id.* at 137:21-138:1.

[16] *See* The role of talc powder exposure in ovarian cancer: mechanistic approach ("budget document"), attached hereto as **Exhibit F.**

[17] Saed Dep. at 497:6-498:6.

provided funds from his department in the form of an account. Those funds covered the costs of "all of the personnel, lab supplies, equipment, services, [and] costs for this project."[18] The PSC was responsible only for the additional time outside of his normal laboratory practice that Dr. Saed worked – overtime, weekends, etc.[19] The aforementioned is significant because Defendants incorrectly imply that Dr. Saed was told by the PSC not to perform certain tests, refusing to accept that Dr. Saed's lab work was independent.[20]

The Budget Document prepared by Dr. Saed contained three specific Aims:

- Determine the effect of talc on the redox balance in normal ovarian surface epithelial and ovarian cancer cells;
- Determine whether exposure to talc can induce point mutations that correspond to known SNPs in key oxidant and antioxidant enzymes as well as BRCA1/2, in normal ovarian surface epithelial and ovarian cancer cells; and,
- Exposure to talc results in neoplastic transformation of normal ovarian surface epithelial cells.[21]

For each of the three Aims Dr. Saed identified a testable hypothesis – a tentative answer to the scientific questions. Although Defendants incorrectly label the testable hypotheses as "an express and emphatic expectation,"[22] only testable

[18] *Id.* at 39:4-40:5.

[19] *Id.*

[20] *See* Defs. Mem. at 8, fn. 17.

[21] *See* Budget Document at 2-3 (emphasis omitted).

[22] Defs. Mem. at 6 (emphasis omitted).

hypotheses can be used to conceive and perform an experiment using the scientific method.[23]

Although the budget document listed a multitude of tests, there was not a need to conduct all of them. "I mean, they're all the same. If you do one, so maybe enough to do – you don't have to do all the oxidated stress marker. You can pick most key one."[24] For example, Dr. Saed testified that "[i]t's a practice in our lab that we use pro-oxidant as myeloperoxidase, iNOS, nitrite, nitrate, and anti-oxidant as SOD, catalase, and glutathiones. So just a normal – it's a – it's a – a practice that we use in the lab.[25] Similarly, in regard to Aim II, although Dr. Saed listed BRCA1 and BRCA2 testing as possible tests, it was not necessary to do it. Those tests can provide clinical value when interpreting data using patients with and without BRCA1, but they are not oxidative stress markers.[26] The same held true for Aim III

[23] Defendants also incorrectly state that Dr. Saed stated that the "goal was to show that treating cells with talc would cause changes in the balance of certain reactive oxygen species" (Defs. Mem. at 1), implying that Dr. Saed set out with a predetermined outcome. However, Defendants fail to provide any citation for their proposition. Instead, Dr. Saed stated that the "***objective is to determine whether talc can induce such mutations***…" *See* Budget Document at 1 (emphasis added).

[24] Saed Dep. at 498:23-499:1.

[25] *Id.* at 499:22-500:1.

[26] *Id.* at 501:14-502:12.

where Dr. Saed did apoptosis and proliferation analysis to look at neoplastic transformation, but did not prepare a neoplastic transformation assay.[27]

2. Dr. Saed's experiment and methodologies

Dr. Saed undertook his research by employing well known methodologies with which he and his laboratory have expertise.[28] As Dr. Saed testified, the tests that formed the foundation of his research are routinely done in his lab, "and we are testing the markers that [we've] been extensively publishing on and testing through the lab… The methodology is in place, it's in the lab, it's been published, it's been referenced, and we test the same markers over and over."[29] Defendants' experts confirmed that the methods employed by Dr. Saed have been previously peer-reviewed and published.[30]

Dr. Saed examined the effect of talcum powder exposure on both normal and ovarian cancer cell lines. All cell lines used in the research were commercially available and the kind used routinely in *in vitro* experiments. For the non-cancerous cells Dr. Saed utilized two human ovarian epithelial cell cultures and the

[27] *Id.* at 503:6-504:3.

[28] *Id.* at 499:2-5.

[29] *Id.* at 137:21-138:18.

[30] *See Birrer* Dep. at 359:18-361:5 (confirming that not only the dosages but the testing used by Dr. Saed's testing has been peer-reviewed and published).

immortalized human fallopian tube epithelial cells (FT22).[31] These cell lines reflect normal ovarian surface epithelial cells and fallopian tube epithelial cells. These are the physiological cell populations from which ovarian cancer is believed to originate[32] and the molecular pathways involved in disease initiation can be investigated in these cells.

Dr. Saed also examined the response of transformed ovarian cancer cell lines, SKOV3, A2780 and TOV112D to talcum powder exposure.[33] Using these tumor cell lines Dr. Saed is able to evaluate the role of direct talcum powder exposure on disease progression.[34] A normal macrophage cell line was used as a non-epithelial cell control, and represents a cell type (macrophage) in which oxidative stress responses and signaling pathways have previously been well delineated.[35]

All of the techniques used by Dr. Saed are broadly used and scientifically valid. He used commercially available ELISAs to measure redox protein levels and

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[31] *See* Saed Publication at 2.

[32] Defendants' experts' publications support this. *See* Vang, R., Shih, I.M. & Kurman, R.J., Fallopian tube precursors of ovarian low and high grade serous neoplasms. *Histopathology* 62, 44-58 (2013).

[33] *See* Saed Publication at 2.

[34] *See* Anglesio, M.S. *et al.*, Type-specific cell line models for type-specific ovarian cancer research. *PloS One* 8, e72162 (2013). *See also* Beaufort, C.M. *et al.*, Ovarian cancer cell line panel (OCCP): clinical importance of in vitro morphological subtypes. *PloS One* 9, e103988 (2014).

[35] *See* Saed Publication at 2.

enzyme activities; the Greiss assay to measure nitrate/nitrite levels; RT-PCR to quantify RNA expression using redox gene specific primers; MTT assay for cell viability; Caspase 3 assays to measure apoptosis and programmed cell death and Taqman-SNP genotyping to identify DNA point mutations induced by talcum powder treatment.[36] The effects of talcum powder were examined across 6 cell lines per assay and samples were assayed in triplicate, which is common laboratory practice.[37]

Dr. Saed maintained the laboratory notebooks for his research contemporaneously and in accordance with standard laboratory practices.[38] All data was collected, analyzed, and recorded according to standard laboratory procedures.[39] To the extent data was created electronically, it was printed and placed into the lab

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[36] *Id.* at 2-3.

[37] *Id.*

[38] Defendants' assertions that the lab notebooks were not maintained contemporaneously are purely speculative and not supported by the record.

[39] Defendants improperly assert that the lab notebooks document "difficulties" and "trouble" encountered by Dr. Saed. (Defs. Mem. at 8). Instead, the lab notebooks document the scientific results of the experiments. For example, nowhere in the record is there evidence that Dr. Saed had "trouble" dissolving talc in DMSO. The lab notebook simply notes that "it won't completely dissolve." *See* Saed Dep. Exhibit 23 ("Pilot Study Notebook") at 1, attached hereto as **Exhibit G**. Nor was it a "difficulty" that the talc at 1000 ug/ml was "physically killing the cells." *Id.* at 19. As Dr. Saed testified, "[p]hysically killing some cells, that doesn't mean you cannot get RNA, you cannot get to do the assay. That doesn't – it's not the optimal condition, but you still can do the experiment, okay. And to confirm that, when we did it with the lower dose, we got the results." *See* Saed Dep. at 392:10-23.

notebook pursuant to standard laboratory practices.[40] All data recorded in the lab notebooks and submitted for peer review and publication was accurate. To the extent errors in the lab notebooks did occur, the errors were inadvertent, non-substantive in nature, and do not affect the veracity or accuracy of the findings. The purported deficits in the lab notebooks identified by Defendants had nothing to do with methodology, data reporting, or conclusions reached and published in manuscript. All relevant portions of the lab notebooks have been provided to Defendants[41] and, although Defendants state that "the record is conflicting on exactly how Dr. Saed conducted his experiment"[42] their memorandum provides a succinct narrative of the work he did.[43] Further, not a single peer reviewer raised concern with the

[40] Dr. Saed testified that most of the work that is done now is done electronically so, just to keep a record in case something happens to the electronic version, the information is printed out and pasted in the lab notebooks. *See* Saed Dep. at 114:22-115:1.

[41] In addition to Pilot Study Notebook Pages, *see also* Saed Dep. Exhibits 1 and 9, attached hereto as **Exhibits H** ("Publication Data") and **I** ("Preliminary Study"), respectively.

[42] Defs. Mem. at 9.

[43] *See* Deft. Mem. at 9-12. On May 23, 2019, following an *in camera* review of non-relevant portions of Dr. Saed's lab notebooks, Judge Pisano ruled that Dr. Saed did not have to produce certain sections previously sought by Defendants. Judge Pisano's Order resolved in the PSC's favor an appeal of Judge Pisano's April 26, 2019 opinion wherein the PSC had challenged the factual findings related to Dr. Saed's notebooks and testimony. Judge Pisano's Order also confirms the arguments raised by Plaintiffs' counsel in prior submissions – that Defendants' efforts were simply meant to harass Dr. Saed – and stand as a further example of Defendants' questionable litigation tactics.

methodologies employed by Dr. Saed and his lab. As Dr. Birrer testified, the peer reviewers did not raise concerns about flaws in the experiments, analysis, or results.[44] As confirmed by Dr. Birrer, reviewers did not find inaccuracies in cell line findings, did not state issues with the cell lines that were used, and did not state that dosages were in appropriate.[45]

Through his experiment Dr. Saed was able to convincingly demonstrate the disruptive effects of talc exposure on redox balance in normal ovarian and fallopian tube epithelial cells, as well as ovarian cancer cell lines. "Talc induces inflammation and alters the redox balance favoring a prooxidant state in normal and EOC cells."[46] Furthermore, talc exposure induced genetic mutations in enzymes regulating the oxidative state, favoring a state of oxidative stress.[47] Cells further exhibited an increase in proliferative rate and viability, and a resistance to apoptosis, which are characteristic of cellular formation.[48]

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[44] *See* Birrer Dep. at 350:19-352:3.

[45] *Id.* at 352:9-17.

[46] Saed Publication at 9.

[47] *Id.* ("[o]ur results confirm an increase in iNOS expression and enzymatic activity in all talc-treated cells… again suggesting the existence of other *NOS2* SNPs.").

[48] *Id.* at 7 ("we have shown that talc enhances cell proliferation and induces an inhibition in apoptosis in EOC cells, but more importantly in normal cells, suggesting talc is a stimulus to the development of the oncogenic phenotype.").

Taken together, the data presented in Dr. Saed's publication indicates that the presence of talcum powder would create conditions which would increase the risk of cellular transformation of normal cells in the ovaries and fallopian tubes, and could be reasonably expected to contribute to the initiation and pathogenesis of ovarian cancer.

C. PUBLICATION OF DR. SAED'S WORK

Dr. Saed's preliminary findings were accepted for publication as an abstract by *Reproductive Sciences* in March 2018. The results of his work, as outlined in the abstract, showed that "[t]here was a marked increase in MRNA levels of the prooxidant enzymes iNOS and MPO in the talc treated ovarian cancer cell lines and normal ovarian epithelial cells, all as compared to their control… Additionally, there was a marked decrease in the mRNA levels of the antioxidant ezymes CAT, GPX, SOD3, but with a marked increase in GSR."[49] Prior to the abstract being accepted, it would have been reviewed "by 4-6 expert reviewers [and] scored according to criteria."[50] The portion of Dr. Saed's experiment related to CA-125 levels was also presented as a poster at the Society for Reproductive Investigation's ("SRI") 65th

[49] *See* Fletcher, N., Talcum Powder Enhances Oxidative Stress in Ovarian Cancer Cells, Reproductive Sciences, March 1, 2018, attached hereto as **Exhibit J.**

[50] *See* Society of Reproductive Investigation, General Abstract Information, SRI 2018 Annual Meeting, attached hereto as **Exhibit K.**

Annual Scientific Meeting in March, 2018.[51] Dr. Saed's work would have been subject to peer-review prior to his poster presentation as well.

In August 2018, Dr. Saed submitted his final manuscript for consideration to *Gynecologic Oncology*. On September 19, 2018, Dr. Saed was informed that the manuscript was not accepted for publication. The e-mail acknowledged that Dr. Saed's work was reviewed by at least two more experts and "while [his] work was not without merit," it was not accepted."[52] After his manuscript was not accepted for publication, Dr. Saed submitted it to *Reproductive Sciences* for peer-review and possible publication, and also submitted it to SRI for consideration as a meeting abstract.[53] In each of these instances Dr. Saed's work would have again been subject to peer-review.

On November 15, 2018, Dr. Saed's abstract relating to SNPs findings was accepted by the Society of Gynecologic Oncology ("SGO") for presentation as a

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[51] *See* Fletcher, N., Talcum Powder Enhances Cancer Antigen 125 Levels in Ovarian Cancer Cells and in Normal Ovarian Epithelial Cells, attached hereto as **Exhibit L.**

[52] *See* September 19, 2018 e-mail to Dr. Ghassan Saed from Robert E. Bristow, MD, Editor, Gynecologic Oncology, attached hereto as **Exhibit M.**

[53] *See* October 10, 2018 *Reproductive Sciences* manuscript submission, attached hereto as **Exhibit N**; October 11, 2018 SRI Abstract Fee Receipt, attached hereto as **Exhibit O.** Dr. Saed's SRI submission was accepted for presentation at the March 2019 Annual Scientific Meeting. *See* Saed Dep. at 484:20-485:17.

poster at the SGO 50th Annual Meeting on Women's Cancer.[54] To be accepted for presentation by SGO, Dr. Saed's manuscript would have been reviewed by an additional 4-5 reviewers for scientific merit and practice relevance. Not long after, his manuscript was reviewed and recommended for publication by *Reproductive Sciences*.[55] The e-mail from *Reproductive Sciences* confirmed that Dr. Saed's work was reviewed, yet again, by at least one additional reviewer[56] It was officially published in February 2019 and is now publicly available.[57]

In total, the work related to Dr. Saed's experiment and his manuscript has been reviewed by approximately 20-25 independent editors and reviewers, and none of the reviewers have been as critical as Defendants' and their paid experts.

D. DR. SAED'S EXPERT REPORT

Dr. Saed's expert report "describe[s] the role of oxidative stress in the pathogenesis and behavior of ovarian cancer as well as describe[s] the biological effects of talcum powder on normal ovarian and fallopian tube cells, macrophages, and ovarian cancer cells."[58] The opinions expressed in his report "are made to a

[54] *See* November 15, 2018 e-mail to Ms. Amy Harper from SGO 2019 Annual Meeting Program Committee, attached hereto as **Exhibit P.**

[55] *See* December 26, 2018 e-mail from Dr. Lawrence Layman, Editor, Reproductive Sciences, attached hereto as **Exhibit Q.**

[56] *Id.*

[57] *See* Saed Publication.

[58] *See* Saed Report at 2.

reasonable degree of scientific certainty and are based on [his] experience, training, and expertise, as well as a knowledge of the relevant scientific literature and [his] previous and ongoing research."[59] Importantly, the experiment performed by Dr. Saed is only part of the basis of his expert report. For example, in his peer-reviewed, published manuscript, Dr. Saed relies upon his experiment and prior work that he has performed in the area of inflammation and oxidative stress in the pathogenesis of ovarian cancer to reach his conclusions.[60] Dr. Saed also clearly distinguishes the *opinions* in his expert report, provided to a reasonable degree of scientific certainty, from the *conclusions* reached in his published paper that are based solely on experimental data presented in the paper. He states conclusions that he has reached about Defendants' products that have resulted from his experiments, but separately states the opinions that he draws based upon those conclusions and his other

[59] *Id.* at 20. *See also* Saed Dep. at 240:17-25 (opinions "based on data from [his] manuscript and this work that [he] did and, also, in published literature that identify the pattern, the signature pro-oxidants in ovarian cancer.").

[60] *See* Saed Publication at 1 ("We have previously characterized EOC cells to manifest a persistent prooxidant state as evident by the upregulation of key oxidants and downregulation of key antioxidants, which is further enhanced in chemo resistant EOC cells."); 7 ("We have previously reported that EOC cells manifest increased cell proliferations and decreased apoptosis."); *Id.* ("We were the first to report that MPO was expressed by EOC cells and tissues and that silencing MPO gene expression utilizing MPO-specific siRNA induced apoptosis in EOC cells through a mechanism that involved the S-nitrosylation and caspase-3 by MPO.") *Id.* ("We have previously highlighted the potential benefits of the combination of serum MPO and free iron as biomarkers for early detection and prognosis of ovarian cancer.").

experiences.[61] Dr. Saed's expert report represents an accumulation of scientific knowledge spanning decades of research and peer-review literature. His opinions are anything but "junk-science" and the Court should permit Dr. Saed to testify.

II. ARGUMENT

The admissibility of expert testimony is determined pursuant to Fed. R. Evid. 702, which incorporates the standards outlined by the United States Supreme Court in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1983).[62] The Third Circuit has distilled Fed. R. Evid. 702 down to three basic inquiries: qualifications, reliability, and fit.[63] The trial court acts as a "gatekeeper" to the admission of expert scientific testimony under Fed. R. Evid. 702 and is tasked with conducting a preliminary assessment "to ensure that any and all scientific testimony… is not only

[61] *See* Saed Report at 20 ("5. In my opinion, based on established molecular mechanisms… 6. In my opinion, based on established molecular mechanisms… (emphasis added)). *See also* Saed Dep. at 244:18-245:12 (testifying to the difference between conclusions expressed in his peer-reviewed, published paper and opinions expressed in his expert report).

[62] The PSC incorporates by reference all arguments contained in *The Plaintiffs' Steering Committee's Omnibus Memorandum of Law In Response And Opposition To Defendants' Johnson & Johnson and Johnson & Johnson Consumer Inc.'s Motion To Exclude Plaintiffs' General Causation Opinions* as well as the *Plaintiffs' Steering Committee's Omnibus Brief Regarding Daubert Legal Standard and Scientific Principles for Assessing General Causation* (ECF. No. 9732).

[63] *JVI, Inc. v. Truckform Inc.*, No. CIV. 11-6218 FLW, 2012 WL 6708169, at *4 (D.N.J. Dec. 26, 2012) (Wolfson, F.) (quotations and citation omitted).

relevant, but reliable."[64] The experiment conducted by Dr. Saed and the opinions expressed by him in his expert report are founded in reliable methodologies and should be permitted.[65]

A. THE METHODOLOGIES EMPLOYED BY DR. SAED IN CONDUCTING HIS EXPERIMENT ARE RELIABLE AND SATISFY DAUBERT STANDARDS

An assessment of the reliability of scientific evidence under Fed. R. Evid. 702 requires a determination as to its scientific validity. In other words, the expert's opinion must be based on the methods and procedures of science rather than on subjective belief or unsupported speculation; the expert must have good grounds for his or her belief. "This does not mean that plaintiffs have to prove their case twice—they do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are *correct*, they only have to demonstrate by a preponderance of evidence that their opinions are *reliable*." [66]

To determine if an expert's testimony is indeed reliable, the Third Circuit has provided some factors district courts should consider:

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[64] *Daubert*, 509 U.S. at 589.

[65] The PSC incorporates by reference all arguments contained in *The Plaintiffs' Steering Committee's Memorandum In Response And Opposition To J&J's Conditional Motion To Exclude Certain Of The PSC's Experts' Opinions For Lack Of Qualifications.*

[66] *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 (3d Cir. 1994) (emphasis in original) (italics added)).

> [(1)] whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses.[67]

The Third Circuit has explained that this list is non-exclusive and trial courts do not need to apply each factor in every single case.[68] In addition, reviewing these factors is also not a simple analysis and a tally of how many of them end up in a party's favor.[69] Rather, in determining whether to admit an expert's opinion, a trial court must thoroughly assess "whether the 'particular opinion is based on valid reasoning and reliable methodology.'"[70] However, the method used by the expert does not always have to be correct. The method just needs to be reliable.[71] "The judge should

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[67] *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 405 (3d Cir. 2003) (citation omitted).

[68] *Elcock v. Kmart Corp.*, 233 F.3d 734, 746 (3d Cir. 2000).

[69] *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 152 (3d Cir. 1999) ("In this regard, a party seeking to exclude (or to admit) expert testimony must do more than enumerate the factors from *Daubert* (and the additional ones from *Paoli*, discussed below) and tally the number that are or are not met by a particular expert's testimony.").

[70] *See Oddi v. Ford Motor Co.*, 234 F.3d 136, 145–46 (3d Cir. 2000) (citation omitted).

[71] *Pineda v. Ford Motor Co.*, 520 F.3d 237, 247 (3d Cir. 2008) ("While a litigant has to make more than a prima facie showing that his expert's methodology is reliable, we have cautioned that the evidentiary requirement of reliability is lower than the merits standard of correctness.") (citations and quotations omitted); *see also Heller*,

only exclude the evidence if the flaw is large enough that the expert lacks 'good grounds' for his or her conclusions."[72]

The factors articulated by the Third Circuit in *In re Paoli* weigh heavily in favor of a finding that Dr. Saed's experiment and opinions are reliable. It is undisputed that the first five factors weigh in favor of Dr. Saed because the methods he employed have been subject to peer review, are generally accepted, have a testable hypothesis, have standards that can control the technique's operation, and have known or calculable rates of error. Defendants' expert, Dr. Birrer, acknowledged that the methodology employed by Dr. Saed in conducting the experiment has been peer reviewed and published in other studies.[73] In fact, another of Defendants' experts, Dr. Mossman, was co-author on a peer-reviewed study which tested asbestos and non-fibrous talc in a similar way.[74] Dr. Saed also testified

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167 F.3d at 152 ("Put differently, an expert opinion must be based on reliable methodology and must reliably flow from that methodology and the facts at issue—but it need not be so persuasive as to meet a party's burden of proof or even necessarily its burden of production.").

[72] *In re Paoli*, 35 F.3d at 746. *See also United States v. Velasquez*, 64 F.3d 844, 849–50 (3d Cir. 1995) ("We have cautioned, however, against applying the reliability requirement too strictly, explaining that the reliability requirement must not be used as a tool by which the court excludes all questionably reliable evidence. The ultimate touchstone of admissibility is helpfulness to the trier of fact.") (quotations and citation omitted).

[73] *See* Birrer Dep. at 359:18-361:5 (testifying that the various tests used by Dr. Saed in his experiment have all be peer reviewed and published).

[74] *See* Shukla, A., et al., Alterations in Gene Expression in Human Mesothelial Cells Correlate with Mineral Pathogenicity, Am J Respir Cell Mol Biol, 41, 114-123

that he has been using the tests that were part of his experiment for decades.[75] The methods have been generally accepted, are broadly used, and are scientifically acceptable. The experiment has a testable hypothesis as any scientist could follow the protocols outlined by Dr. Saed in his lab notebooks and manuscript and test the results.[76] When asked, Defendant's expert, Dr. Mossman, refused to answer the question of whether she *could* replicate Dr. Saed's experiment, an obvious question because she has previously conducted and proposed similar studies, opting instead to only state that she would not want to and that she would do it differently.[77] Wanting to do the experiment differently and not being able to replicate what was done are two different things, and Defendants' experts tacitly confirm that Dr. Saed's work can be replicated. The common acceptance of the techniques supports a finding that there are standards controlling the technique's operation and, lastly, error rates

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(2009), attached hereto as **Exhibit R** (exposing human mesothelial cells and immortalized cell lines to asbestos and non-fibrous talc samples and examining for changes in gene expression). In 2009, Dr. Mossman had also proposed conducting a study of gene expression changes in human ovarian epithelial cells exposed to talc of different sources and mineralogy. She was going to conduct the cell assay and gene expression analysis. *See* IMERYS 248635, September 25, 2009, Regulatory Science Project Proposal, attached hereto as **Exhibit S**.

[75] *See* Saed Dep. at 138:15-19 (explaining that the methodology used in the lab has been in place and have been published and referenced and been done over and over).

[76] Although an option, none of Defendants' experts conducted a similar study to challenge the hypotheses or results of Dr. Saed's experiment.

[77] *See* April 8, 2019 Deposition of Brooke T. Mossman, M.S., Ph.D. ("Mossman Dep.") at 496:9-498:24, excerpts of which are attached hereto as **Exhibit T.**

are calculable. The aforementioned results, therefore, have five factors weighing heavily in favor of Dr. Saed.

Defendants have argued that the remaining factors – technique, qualifications and non-judicial issues weigh heavily against permitting Dr. Saed to testify. However, as outlined below, Defendants' criticisms of Dr. Saed have no factual underpinnings.

1. Dr. Saed's experiment and opinions are not "made-for-litigation"

Defendants' argument that Dr. Saed's opinions were driven by litigation and reflect highly unscientific practices ignores Dr. Saed's professional experience, the scrutiny placed on his work by multiple editors and reviewers, and the similar work that has been done by others.[78] To start, as noted in his expert report, Dr. Saed "undertook research to determine whether or not there was a molecular basis for the observed association between talcum powder and ovarian cancer."[79] "Issues like this one, relating to the pathogenesis of ovarian cancer and the relationship between inflammation and other pathological conditions in the female reproductive system as well as cancer, ***have been the focus of [his] laboratory for years***."[80] Dr. Saed was

[78] *See* Defs. Mem. at 29. As noted above, Defendants' assertions that Dr. Saed's work is fraudulent are baseless and designed as an unwarranted character attack.

[79] Saed Report at 13.

[80] *Id.*

not diving into uncharted waters when he began this process. Dr. Saed set out to conduct an experiment involving a subject matter with which he had expertise, as reflected by his authorship on numerous studies published in peer-reviewed journals, and which has been the focus of his laboratory for years – many relating to oxidative stress in the pathogenesis of ovarian cancer.[81] Tellingly, the costs of the experiment were paid for by Dr. Saed through his laboratory budget because it was a subject he wanted to investigate, not because he was driven to do so by litigation.[82] Further, Dr. Saed testified that he was not driven by the results of the litigation – his intention was to publish the results regardless of the outcome because it was an important topic area.[83]

Although the opinions have been presented for purposes of litigation, they are far from unscientific and are founded in sound methodology. All of the techniques utilized by Dr. Saed in his experiment are broadly used and scientifically acceptable. As previously noted, similar techniques were employed by Shukla (with Defense expert Mossman as co-author). Similar techniques have also been employed by

[81] *Id.*at 2-3.

[82] *See* Saed Dep. at 38:1-39:21.

[83] *Id.* at 147:8-15 (noting that he was being paid to do the work regardless of whether the results were positive or negative); 327:3-6 (he would have published his results whether positive or negative); and 336:21-337:18 (still would have published the results even if it showed no biological effect because, either way, the findings are "huge.").

Buz'Zard (2007) and Akhtar (2010 and 2012). These experiments, like that of Dr. Saed, were peer-reviewed and published in reputable scientific journals.[84]

Lastly, far from "unscientific," Dr. Saed's work has been the subject of four multiple accepted abstracts, has been published in a peer-reviewed scientific journal, and has been presented at prestigious medical conferences. In each instance Dr. Saed's work was peer-reviewed and approved by editors and reviewers prior to its presentation or publication. With or without the form of disclosures that Defendants argue were necessary, for Dr. Saed's work to withstand these review processes undercuts any arguments that the work was "unscientific" and "made-for-litigation." Even the reviewers at *Gynecologic Oncology*, who Defendants argue are Dr. Saed's

[84] *See* Buz'Zard, A, Pycnogenol reduces Talc-induced Neoplastic Transformation in Human Ovarian Cell Cultures, *Phytother. Res.* 21, 579-586 (2007) (treating cells with talcum powder and noting that talc increased proliferation, decreased the number of transformed colonies and decreased the ROS generation in the ovarian cells, possibly contributing to ovarian carcinogenesis), attached hereto as **Exhibit U**; Akhtar, MJ, et al., The Primary role of iron-mediated lipid peroxidation in the differential cytotoxicity cause by two varieties of talc nanoparticles on A_{549} cells and lipid peroxidation inhibitory effect exerted by ascorbic acid, *Toxicology*, 24, 1139-1147 (2010) (*in vitro* assessment of talc for potential toxicity via use of assays and measuring cytotoxicity and oxidative stress), attached hereto as **Exhibit V**; and Akhtar, MJ, et al., Cytotoxicity and Apoptosis Induction by Nanoscale Talc Particles from Two Different Geographical Regions in Human Lung Epithelial Cells, *Environ. Tech.* (2012) (measuring oxidative stress and cell apoptosis via cell analysis), attached hereto as **Exhibit W**.

only "relevant" peers,[85] found that Dr. Saed's work was "a well-written manuscript and the conclusions are supported by the results."[86]

The case cited by Defendants to support their position only bolster the PSC's argument that these attacks are unfounded. In *Wade-Greaux v. Whitehall*, the court did exclude the experts' testimony because it was "litigation driven." Instead, the opinions were excluded because the experts had relied upon insufficient data – testing only 16 rabbits where some dose groups contained only a single rabbit, and reasonable conclusions could not be drawn from the limited information.[87] In *In re Opus E., LLC*, the bankruptcy court refused to admit expert testimony where the expert revised and adjusted the debtor's projections to better fit into the expert's opinions.[88] Neither case is on point with the present matter and Defendants' argument that Dr. Saed's work was litigation driven is unfounded and should carry no weight.[89]

[85] *See* Defs. Mem. at 79.

[86] *See* **Exhibit M**.

[87] *Wade-Greaux v. Whitehall Labs., Inc.*, 874 F. Supp. 1441, 1460 (D.V.I. 1994).

[88] *In re Opus E., LLC*, 528 B.R. 30, 55 (Bankr. D. Del. 2015).

[89] Defendants' heavy reliance on *Wade-Greaux* to support their position underscores just how far afield their arguments are.

2. Dr. Saed did not predetermine the conclusions he expected to reach

Defendants' argument that Dr. Saed predetermined the conclusions of his work and then designed experiments to prove them demonstrates Defendants' fundamental lack of scientific knowledge and awareness. Defendants' argument is premised on Dr. Saed's statements within the Budget Document of what he "expected" the outcomes to be.[90] However, far from being predetermined conclusions, each of the "expectations" stated by Dr. Saed is a testable hypothesis – a tentative answer to the scientific questions.

"A testable hypothesis is a hypothesis that can be proved or disproved as a result of testing, data collection, or experience. ***Only testable hypotheses can be used to conceive and perform an experiment using the scientific method***."[91] As recognized in the cases cited by Defendants, "[c]ertainly, scientists may form initial tentative hypotheses."[92] It is when a scientists "conviction about the ultimate conclusion of their research is so firm that they are willing to aver under oath that it is correct prior to performing the necessary validating tests" that objectivity is lost.[93]

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[90] *See* Budget Document at 2-3.

[91] *See* https://www.thoughtco.com/testable-hypothesis-explanation-and-examples-609100 (emphasis added), last visited May 24, 2019.

[92] *Claar v. Burlington N. R. Co.*, 29 F.3d 499, 503 (9th Cir. 1994).

[93] *Id.*

Defendants offer no evidence that Dr. Saed was without the objectivity necessary to faithfully abide by the scientific method. In fact, Dr. Saed testified that part of the reason for his conducting the experiment was because he wanted to find out ***if*** there is molecular evidence.[94] He did not approach his experiment with the preconceived plan of showing that there ***was*** molecular evidence. Dr. Saed would have published his findings even if they did not demonstrate a biological effect.[95]

Defendants ignore that Dr. Saed's Budget Document set out specific Aims, none of which presupposed any conclusions. The Aims sought to make determinations by way of the experiments outlined in the Budget Document. For example, **Aim I** sought to "[d]etermine the effect of talc on the redox balance in normal ovarian surface epithelial and ovarian cancer cells."[96] The Aim outlined the testing methods that could be used "to accomplish the this aim…" but presuppose no outcomes. Each of the three Aims stated in Dr. Saed's budget document outline the scientific methods and procedures to be implemented in order to reach ultimate

[94] *See* Saed Dep. at 276:15-20 ("I agreed in principle to serve as a consultant for what I am an expert in, which is oxidative stress and ovarian cancer, and I promised to run data, do some work, ***because I wanted to find out if there is molecular evidence*** to support the effect of talcum powder on the markers that I study, which are the markers of risk of ovarian cancer." (emphasis added)).

[95] *Id.* at 327:3-7 (Q. Would you have published your results even if they had shown there was no biological effect?... A. Of course.").

[96] *See* Budget Document at 2.

conclusions and do not identify any prior, subjective beliefs. Dr. Saed's process is a very common practice, especially when writing grant requests.

Case law relied upon by Defendants demonstrate the chasm between their arguments and the facts of the case. In *Claar*, for example, the district court excluded the experts' opinions because they had "formed their opinions before reading the relevant literature" despite not being "familiar with the field to diagnose the causes of plaintiffs' injuries without first reviewing that literature.[97] In *Snodgrass*, expert opinions were excluded after the expert testified to an arbitrary division of data into subsets that "served the purpose" of achieving the desired result.[98] Dr. Saed's use of the term "expect" in a budget document in no way represents a conclusion driven predetermination and certainly does not rise to the levels of conclusion driven analysis observed in the cases cited by Defendants.

3. The methods followed by Dr. Saed were sound and his causal conclusions are a direct product of his sound methodology

[97] *Claar*, 29 F.3d at 502.

[98] *Snodgrass v. Ford Motor Co.*, No. 96-1814 (JBS), 2002 U.S. Dist LEXIS 13421, at *43 (D.N.J. Mar. 28, 2002). *See also In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, 858 F.3d 787, 798 (3d Cir. 2017) (rejecting the reanalysis of studies, without explanation, to obtain result of statistical significance).

Defendants make much of the fact that Dr. Saed did not perform ***every*** test that was identified in his Budget Document.[99] However, as Dr. Saed specified in his deposition, the Budget Document was prepared in order to determine how much all experiments would cost if they were to be done.[100] It represented Dr. Saed's thinking leading up to the experiment, but did not represent the experiment protocol or methodology that Dr. Saed intended to employ. As Dr. Saed noted in regard to the various tests listed under the different Aims, "they're all the same. If you do one, so maybe enough to do – you don't have to do all the oxidated stress marker. You can pick the most key one."[101] The various tests and assays included in each Aim address the same general topic. As Dr. Saed testified, he did not necessarily need to perform each and every one – he picked the "most key one". There is nothing in the record suggesting that Dr. Saed selectively performed tests to reach desired outcomes.

In regard to **Aim III,** which is the focus of Defendants' argument that Dr. Saed did not follow his own methodology,[102] Dr. Saed did perform the apoptosis and

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[99] *See* Defs. Mem. at 33-34 (arguing that findings are unreliable because Dr. Saed did not perform critical testing and apply his own methodology).

[100] *See* Saed Dep. at 497:15-17.

[101] *Id.* at 498:23-499:1.

[102] Defendants incorrectly conflate apoptosis and proliferation testing with transformation assays, assuming that the transformation assay is a "test." *See* Saed Dep. at 512:14-19 (highlighting counsel's confusion regarding "the test method involving suspended cells in agar" when, in fact, the transformation assay is a culture that would be subject to apoptosis and proliferation testing).

proliferation analysis.[103] As outlined in the budget document, apoptosis was evaluated by measuring the levels of caspase-3, a marker of programmed cell death. This testing was done using a commercially available kit that is generally accepted and routinely used in *in vitro* testing. Decreased apoptosis (increased cell survival) was observed upon talcum powder exposure in all cell lines tested, and the effect was dose-dependent.[104] Cells further exhibited an increase in proliferative rate and viability, and a resistance to apoptosis, which are characteristic of cellular transformation. Taken together, the data presented in Dr. Saed's publication indicate that the presence of talcum powder would create conditions which could increase the risk of cellular transformation of normal cells in the ovaries and fallopian tubes, and could be reasonably expected to contribute to the initiation and pathogenesis of ovarian cancer.

Importantly, although Defendants argue that Dr. Saed did not follow a methodology to support his causal conclusions, multiple editors and scientists who have peer-reviewed his work have found differently. Even the reviewers at *Gynecologic Oncology*, who Defendants have deemed the only "relevant peers," noted that Dr. Saed's conclusions are supported by the results of his work.[105] All

[103] *Id.* at 503:20-504:3.

[104] *See* Saed Publication at 8.

[105] *See* **Exhibit M**.

reviewers were aware of and able to assess the materials and methods used in the experiment and, contrary to Defendants' position, not a single independent source had issue. It is only Defendants and the made-for-litigation opinions of their experts who raise issues, and those with issues are in the minority.[106]

4. Defendants' Dose Response Arguments Are Inapplicable To Tests Regarding Molecular Mechanism

Defendants' argument that Dr. Saed's experiment is not reliable because it failed to consider a dose of talc relevant to perineal talc use is based upon an improper premise. The objective of Dr. Saed's experiment was not to extrapolate *in vitro* results to determine whether the use of talcum powder ***causes*** ovarian cancer in humans. Nor was the objective of the experiment to determine whether the use of talcum powder poses an ***increased risk*** of ovarian cancer.[107] Instead, "[t]he

[106] In *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256 (2d Cir. 2002), the court excluded evidence where the expert failed to apply the stated methodology "reliably to the facts in the case." *Id.* at 269. Comparatively, the methodologies outlined in Dr. Saed's manuscript were reliably applied and Dr. Saed expressed conclusions that were supported by the results of his work. In *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434 (W.D. Pa. 2003), the court excluded experts who abandoned scientific method, finding that their opinions were "more subjective than scientific methodology." *Id.* at 560. Nothing related to the experiment performed by Dr. Saed can be considered "subjective."

[107] The cases cited by Defendants in support of their argument all focus on human causation. *See In re Zoloft (Sertraline Hydrocloride) Prod. Liab. Litig.*, 26 F. Supp. 3d 466, 478 (E.D. Pa. 2014) (requiring that dose be addressed when considering human causation); *Bourne ex rel. Bourne v. E.I. Dupont de Nemours & Co.*, 189 F. Supp. 2d 482, 495 (S.D.W. Va. 2002) (excluding opinion that benomyl is teratogenic in humans based solely upon *in vivo* animal studies and *in vitro* tests); *In re Diet*

objective of th[e] study was to determine the effects of talcum powder on the expression of key redox enzymes, CA-125 levels, and cell proliferation and apoptosis in normal and [epithelial ovarian cancer] cells."[108] Determination of a relevant dose was not necessary. However, to the extent doses may be relevant, the doses used by Dr. Saed were similar to those used in studies conducted by Shukla (co-authored by Dr. Mossman), Buz'Zard, and Akhtar, none of which undermine the findings of Dr. Saed's experiment.[109]

Standing alone, *in vitro* studies are not designed to mimic dosage in humans. *In vitro* tests do, however, "provide useful information about metabolic processes at

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Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig., No. MDL 1203, 2000 U.S. Dist. LEXIS 9661, at *26 (E.D. Pa. June 28, 2000) (excluding opinions of human causation based only on *in vitro* animal studies at dose concentrations significantly higher than ingested by humans); *Wade-Greaux*, 874 F. Supp. At 1480 (holding scientifically invalid the notion that one can accurately extrapolate from animal data to humans to prove causation without supportive positive epidemiology).

[108] Saed Publication at 4.

[109] *Compare* **Exhibits R, U, V**, and **W** (Dr. Saed's dosages at levels lower than those used by Buz'Zard and Akhar, and comparative to Shukla when conversions are done to account for micrometers per centimeters squared versus micrometers per cubic centimeter). Defendants' expert, Dr. Mossman, testified that those doses are "appropriate concentration levels to determine pathogenicity of asbestos and talc." Mossman Dep. at 355:1-358:13. Dr. Mossman't testimony undercuts the arguments put forth by Defendants' expert, Dr. Boyd, that Dr. Saed was using "enormous" doses. *See* February 25, 2019 Expert Report of Jeffrey Boyd For General Causation *Daubert* Hearing ("Boyd Report") at 4, attached hereto as **Exhibit X.**

a cellular level, and may supplement existing animal and human data."[110] *In vitro* studies or studies in cell culture may be conducted and are an important part of the totality of the evidence and the determination of general causation.[111] If results from both epidemiologic and toxicologic studies have been produced, "no universal rules exist for how to interpret or reconcile them."[112] However, both can be considered—"careful assessment of the methodological validity and power of the epidemiologic evidence must be undertaken, and the quality of the toxicologic studies and the questions of interspecies extrapolation and dose–response relationship must be considered."[113] Therefore, Dr. Saed's cellular experiments are not considered unreliable because he did not attempt to determine and use a dose relevant to the question of human causation.

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[110] *Bourne ex rel. Bourne*, 189 F. Supp. 2d at 496.

[111] *Reference Manual on Scientific Evidence*, Fed. Judicial Ctr., 592 (3d ed. 2011) (hereinafter *Ref. Man.*) at 623, 674. *See also* Mossman BT, Mechanistic in vitro studies: What they have told us about carcinogenic properties of elongated mineral particles (EMPs). *Toxicol. Appl. Pharmacol.*, 2018 Dec. 15; 361:62-67 ("*In vitro* studies using target and effecter cells of mineral-induced cancers have been critical in determining the mechanisms of pathogenesis as well as the properties of elongated mineral properties (EMPs) important in eliciting these responses.").

[112] *Id.* at 564.

[113] *Id.* at 564-565.

5. Dr. Saed utilized appropriate and valid controls

Contrary to Defendants' argument, Dr. Saed did use valid controls when conducting his experiments. As explained by Dr. Saed, "sterile DMSO was used as a control for all treatments."[114] To do so, talcum powder was taken and mixed with DMSO. Cells were then treated with DMSO alone ("untreated" cells) and with the mixture of DMSO and talcum powder ("treated" cells). The treated cells were further exposed to different doses of talcum powder to determine dose-response. To the extent DMSO had any effect on the cells the response would have been seen in the untreated cells.[115] These conditions represent an appropriate control for an *in vitro* study.

Defendants' argument regarding the absence of valid controls is a red herring. No evidence is offered that the combination of DMSO and talc interacted in a way that skewed the results of Dr. Saed's experiments. To the extent that Defendants' expert, Dr. Boyd, opined that "recent research suggest that DMSO could interact with talc and 'alter the effect that talc would otherwise have on the cells (if any),'"[116] the opinion is without basis. Dr. Boyd's testimony was actually to the contrary,

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[114] Saed Publication at 5.

[115] *See* Saed Dep. at 273:8-13.

[116] Defs. Mem. at 38-39, quoting Boyd Report at 4 (citing Hall et al., *Say No to DMSO: Dimethyl Sulfoxide Inactivates Sisplatin, Carboplatin, and Other Platinum Complexes*, 74(14) Can Res. 3913 (2014)).

agreeing that DMSO is a "virtual, universal solvent" and stating that he had no knowledge of whether DMSO interacts with talc and has no evidence that DMSO renders talcum powder unstable.[117]

The same holds true for Defendants' criticisms related to Dr. Saed's reliance on colormetric assays. Defendants' argue that Dr. Saed offered no evidence to support his assertion that the techniques used to "wash" cells of all talc prior to testing were failsafe.[118] However, Defendants offered no evidence that particulates may be present on the cells after washing. As Dr. Saed testified, "when we measure colormetric assay for proteins, these were proteins extracted from cells. They have no – nothing from outside, no talc, no powders, nothing else. This is total protein extracted from lysate of cells, so whatever is in the cells can interfere with the assay… but outside, no, because there is no outside source."[119] Dr. Saed went on to explain that the generally accepted methodology that has been around for a half-century is a methodology that "you treat, you wash the cells, the cells are alive, you wash them, and then you lyse them, and then you extract proteins… It only carries proteins, and you go through different phases of purification until you extract total

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[117] *See* April 8, 2019 Deposition of Jeffrey A. Boyd, Ph.D. ("Boyd Dep") at 236:16-21 (agreeing that DMSO is a virtual, universal solvent); and 238:10-16 (stating that he has no knowledge that DMSO interacts with talc or renders talcum powder unstable), excerpts attached hereto as **Exhibit Y.**

[118] *See* Defs. Mem. at 41.

[119] Saed Dep. at 440:14-20.

proteins. And this is very standard method."[120] Defendants ask the Court to rule out five decades of established and accepted methodology based upon nothing but pure speculation that the established practices may not work.

Defendants are also unable to offer any literature citation for the proposition that using "glass beads" as a control provides value, except for the study conducted by their own expert, Dr. Brooke Mossman.[121] There is no literature to suggest that tissue does not react to glass beads. Further, there are significant differences in the size and morphology of glass beads and talcum powder, thereby undermining actual consistency and control. Dr. Saed's choice for control was not novel. Other peer-reviewed published molecular studies did not use glass beads (or any other particulate) as a control; rather, they used "no talc." For example, in Buz'Zard statistical significance was determined comparing the treatment with the respective untreated control.[122] Likewise, in both studies authored by Akhtar, "cells not exposed to particles served as controls in each experiment."[123] Lastly, not a single independent editor or reviewer commented that Dr. Saed's method of using "no talc"

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[120] *Id.* at 441:9-18.

[121] *See* Shukla, **Exhibit R**.

[122] *See* Buz'Zard, **Exhibit U** ("the percent cell viability was calculated as the absorbance of the treated cells divided by the absorbance of untreated cell multiplied by 100).

[123] *See* Akhtar (2010), **Exhibit V** at 1140; Akhtar (2012), **Exhibit W** at 396.

as a control was inappropriate. In sum, Defendants' arguments regarding Dr. Saed's controls are based upon unsupported hypotheticals that challenge the validity of generally accepted scientific techniques.

As with all other arguments raised by Defendants, the case law relied upon in support of their contentions demonstrates their weakness. For example, in *Mancuso v. Consol. Edison Co. of N.Y.*, the expert failed to use comparable subjects when conducting cell testing, relying upon cells from adult plaintiffs and foreskin of infants as a control.[124] No such control gap exists here.

6. Dr. Saed's use of multiple cell lines and multiple dose treatments across each cell line undercuts Defendants' arguments regarding reproducibility

Dr. Saed has adequately demonstrated that the results of his work are reproducible. Dr. Saed's experiment involved the use of six cell lines.[125] Each cell line was then separated into four separate culture dishes and treated – control; 5; 20;

[124] *See Mancuso v. Consol. Edison Co. of New York*, 56 F. Supp. 2d 391, 403 (S.D.N.Y. 1999). The other cases cited by Defendants do not even concern issues with proper control. In *In re Mirena Ius Levonorgestrel-Related Prod. Liab. Litig. (No. II)*, 341 F. Supp. 3d 213 (S.D.N.Y. 2018), for example, the expert was excluded because, as the basis for his opinion, he continued to rely upon a study that had been repudiated by the author after discovering a design flaw. The expert's reliance continued despite the corrected data from the study opposite results. Likewise, the issue in *Wade-Greaux* related to the expert's failure to use appropriate sample sizes and failure to account for multiple alternative factors.

[125] *See* Saed Dep. at 124:7-9 (noting six cell lines, each done in triplicate); Saed Report at 13 (identifying six cell lines – SKOV-3; A2780; TOV112D; EL-1; FT33).

and 100 ug/mL.[126] After the cells were treated for 72 hours, culture media was collected for analysis. Each culture media was tested in triplicate.[127] As a result, excluding the control, each cell line was separated into three independent culture dishes (triplicate) and then tested three times (triplicate), "a triplicate of a triplicate." The results were consistent across talc treated cells.[128]

Defendants' argument ignores that the each of the cell lines were initially separated into four separate culture dishes so that each cell line was treated in triplicate. As Defendants do correctly note, Dr. Saed then measured each of the triplicate cell lines in triplicate.[129] Defendants' use of "fuzzy math" to undercut the methods employed by Dr. Saed is unavailing. The replication of results by Dr. Saed across multiple cultures of multiple cell lines demonstrates reproducibility far beyond that which courts have found to be lacking in the cases relied upon by Defendants. In *Rovid v. Graco Children's Prods., Inc.*, for example, the expert's

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[126] *See* Saed Dep. at 125:19-22; Saed Publication at 2 ("Sterile DMSO was used as a control for all treatments. Cells were seeded in 100-mm cell culture dishes… and were treated 24 hours later with 5, 20, or 100 ug/mL of talc for 72 hours.

[127] *Id.* at 125:3-126:4.

[128] *See* Manuscript at 9 ("We have shown a dose-dependent significant increase in key prooxidants… and a concomitant decrease in key antioxidant enzymes… ***in all talc-treated cells*** (both normal and ovarian cancer) compared to their controls." (emphasis added)).

[129] *See* Defs. Mem. at 43 ("He then ***measured his results*** three times." (emphasis in original)).

methodology was found to be insufficient because he performed only a single test.[130] Likewise, in *Avon Prods., Inc. v. S.C. Johnson & Sons, Inc.*, the expert tried to rely upon a mosquito test in which subjects were exposed to mosquitos only a single time while repellent was applied. The court determined that there was no way to assess how changing factors ***outside the lab*** may have impacted results if tests were run on multiple occasions.[131] It is for these reasons that Defendants' arguments premised on reproducibility must fail.

7. The cell lines utilized by Dr. Saed were appropriate and fit within his methodology

Defendants erroneously argue that Dr. Saed studied cell lines that could not possibly support his conclusions on biological mechanism and causation because they were cells of irrelevant origin, immortalized or already cancer cells. To start, Defendants argument is wrong because Dr. Saed did use "normal human cells from the target organ" as Defendants demand. As outlined in his published manuscript, Dr. Saed used six different cells in his experiment: (3) ovarian cancer cell lines;

[130] *Rovid v. Graco Children's Prods., Inc.*, 17-cv-015606-PJH, 2018 U.S. Dist. LEXIS 192449, at *14 (N.D. Cal. Nov. 9, 2018).

[131] *Avon Prod., Inc. v. S.C. Johnson & Son, Inc.*, 984 F. Supp. 768, 787 (S.D.N.Y. 1997). *Koch v. Shell Oil Co.*, 49 F. Supp. 2d 1262, 1268 (D. Kan. 1999) is inapplicable to the present matter. In *Koch*, the expert testified that the testing samples had been destroyed during a lab move and so the experiments could not be reproduced.

normal cells human macrophages; immortalized human fallopian tube secretory epithelial cells; and ***human primary normal ovarian epithelial cells***.[132]

Regardless, as with their argument regarding dose response, Defendants ignore the objective of Dr. Saed's experiment and make arguments relevant only to extrapolation of *in vitro* studies to human causation. Defendants' reliance on *In re Rezulin*, wherein the court warned that "[c]aution always must be used in ***extrapolating*** results in tissue culture to ***effects in live humans***," exemplifies their obtuseness.[133] As previously noted, the objective of Dr. Saed's experiment was not to extrapolate *in vitro* results to determine human causation, but to "determine the effects of talcum powder on the expression of key redox enzymes, CA-125 levels, and cell proliferation and apoptosis in normal and [epithelial ovarian cancer] cells."[134] *In vitro* tests "provide useful information about metabolic processes at a cellular level, and may supplement existing animal and human data."[135] *In vitro* studies or studies in cell culture may be conducted and are an important part of the

[132] *See* Saed Publication at 2 (emphasis added).

[133] *In re Rezulin Prod. Liab. Litig.*, 369 F. Supp. 2d 398, 428–429 (S.D.N.Y. 2005) (emphasis added). *See also Mancuso*, 56 F. Supp at 403 (noting necessity of establishing dose response relationship before determining human causation).

[134] Saed Publication at 4.

[135] *Bourne ex rel. Bourne*, 189 F. Supp. 2d at 496.

totality of the evidence and the determination of general causation.[136] Therefore, regardless of the type of cell lines used, Dr. Saed's results provide valuable insight into determining general causation. Lastly, Defendants' arguments related to this issue also fail because even if Dr. Saed had only used immortalized cells, use of such cells have been noted to be near the top of the hierarchy when it comes to relevance of experiments, just below primary human cells.[137]

8. The results from SNP data are consistent with experimental methods and are reliable

Defendants incorrectly argue that Dr. Saed's conclusions regarding his SNP data are unreliable.[138] Defendants' position looks at the data from Dr. Saed's experiment and fails to consider the other research conducted by Dr. Saed, and referred to in his manuscript for the proposition that specific gene mutations occur as a result of exposure to talcum powder. For example, in his peer-reviewed published manuscript Dr. Saed concludes that the data from his experiment "confirm an increase in iNOS expression and enzymatic activity in all talc treated cells."[139] Dr. Saed goes on to state that "***[c]ollectively***, these findings support the notion that

[136] *Reference Manual on Scientific Evidence*, Fed. Judicial Ctr., 592 (3d ed. 2011) (hereinafter *Ref. Man.*) at 623, 674.

[137] *See In re Rezulin*, 369 F. Supp. 2d at429 ("At the top of the hierarchy is human hepatocytes. Next is "immortalized" hepatocytes…").

[138] *See* Defs. Mem. at 46.

[139] Saed Publication at 9.

talc treatment induced gene point mutations that happen to correspond to SNPs in locations with functional effects, thus altering overall redox balance for the initiation and development of ovarian cancer."[140] The manuscript does not state, as Defendants imply, that genetic mutations occurred and cells were transformed during the 72-hours that cells were exposed to Defendants' talcum powder. Instead, when read properly (and "collectively"), Dr. Saed's manuscript notes that "we have ***previously*** reported that acquisition of chemoresistance by ovarian cancer cells is associated with a switch from the *GPXI* SNP genotype to the normal *GPXI* genotype" and those findings, coupled with the increase iNOS expression, enzymatic activity, and suggested existence of *NOS2* SNPs found in the experiment, support his conclusions about talc treatment induced gene point mutations.

When asked whether his manuscript was reporting that talc causes mutations in DNA in 72 hours Dr. Saed clarified that "there is an ***induction*** of this specific mutation in response to the treatment of talc."[141] He did not state that the mutation had occurred or, as Defendants' expert, Dr. Neel, stated a "wholesale change in [the] genetic content of a specific… SNP within 72 hours."[142] Importantly, genotoxicity can be demonstrated within 72 hours, but cells cannot be transformed within that

[140] *Id.* (emphasis added).

[141] Saed Dep. at 251:4-14 (emphasis added).

[142] Defs. Mem. at 48.

time, and Dr. Saed has not attempted to assert anything different. It is for this reason that Defendants' arguments that Dr. Saed results lack coherent support are unfounded.[143]

As is a common theme throughout, Defendants argue that it is only Defendants' experts and the reviewers for *Gynecologic Oncology* who have the expertise to understand the alleged errors in Dr. Saed's experiment.[144] Defendants' arrogance actually compels the assertion that other "reviewers lack the expertise needed to understand."[145] However, the aforementioned statement failed to consider that those included amongst the reviewers that "lack the expertise" are peer-reviewers who accepted Dr. Saed's abstract reporting his SNP findings for presentation at the Society for Gynecologic Oncology's 50th Annual Meeting on Women's Cancer!

In the end, Defendants are unable to dismiss the fact that Dr. Saed's body of work related to oxidative stress and ovarian cancer over the past several decades combined with the results of his recent experiment has enabled him to define a biologically plausible pathway by which Defendants' talcum powder products can

[143] *Id.* at 49-50.

[144] *Id*. at 49-50.

[145] *Id.* Defendants' view from their self-appointed throne has also enabled them to determine that the reviewers from *Gynecologic Oncology* were "confused" and "expressed doubts" despite the absence of any such statements. *Id.*

induce ovarian cancer. His findings have been peer-reviewed and accepted by numerous experts in the field, enabling him to publish his results, present at prestigious conferences and have his abstracts accepted on multiple occasions.

9. Any errors identified in Dr. Saed's lab notebooks were inadvertent, non-substantive in nature, and do not affect the veracity or accuracy of the findings

Any errors contained in Dr. Saed's lab notebooks were inadvertent, non-substantive and, most importantly, have no impact on the accuracy or veracity of his findings. As an initial matter, as Dr. Saed testified, most of the work that is done now is done electronically so, just to keep a record in case something happens to the electronic version, the information is printed out and pasted in the lab notebooks.[146] The underlying data, therefore, is maintained electronically.

As it relates to white-out, Dr. Saed acknowledged that the use of white out is not a standard practice and is not one that he teaches to those who work in his lab.[147] However, to the extent white out was used in the lab notebook, it had no impact on the accuracy or veracity of data.[148] The areas where white out did appear related to

[146] *See* Saed Dep. at 114:22-115:1.

[147] *Id.* at 99:21-25 (typically would not use white out); 102:9-16 (would have preferred that the white out was not used, but it was. That said, it doesn't change anything); 109:24-110:4 (Dr. Saed would have preferred that it not happen, but it did); 115:6-116:9 (instructed the people within the lab on how to maintain a notebook and white out should not have been used).

[148] *Id.* at 100:5-13 (White out has nothing to do with results).

procedures in the lab and did not impact data or results. It pertained to procedures that have been published over one hundred times.[149] Defendants are unable to offer any evidence that the areas of white out were substantive or had any impact on the results that have been peer-reviewed and published.[150]

Accusations as to mathematical calculations are also unavailing. As indicated above, the data related to the work done by Dr. Saed is done electronically and maintained electronically. Handwritten notes in the lab notebook that are mathematical would be just that – notes. The relevant data and results are all calculated electronically and were the data that was reported in the publication. Further, while Defendants argue that there are variations in prior ***drafts*** of manuscripts, that may explain why the manuscripts were ***drafts***. Defendants simply attempt to inflate insignificant issues in an effort to undercut the work of Dr. Saed. Defendants' challenges simply do not rise to the level that would warrant exclusion under relevant case law.

[149] 98:19-23 (white out appeared on a summary of procedures that have been published over one hundred times); 101:8-19 (about procedures that have previously been published).

[150] Defendants reference to statements by Judge Pisano that Dr. Saed "was shown to be less than forthcoming" should carry no weight. Defs. Mem. at 52. The PSC objected to the order referenced by Defendants because it was based on factual error and the issues related to the Order were subsequently resolved in favor of the PSC.

In *Louis Vitton Malletier v. Dooney & Burke*, 525 F. Supp. 2d 558 (S.D.N.Y. 2007), for example, the court excluded the expert's report where it was found that the expert had committed ***significant methodological errors***.[151] In contrast to *Louis Vitton*, Defendants are unable to point to significant methodological errors and, to the extent Defendants have raised issue with Dr. Saed's methods, those issues have been addressed, *supra*.[152]

Errors in an expert's work goes to the weight of the evidence and an analysis of errors should be left to the trier of fact.[153] The *Daubert* analysis focuses on the methodology underlying an expert's opinion, not the expert's conclusions.[154] Therefore, the focus of admissibility under *Daubert* is the reliability of the experts'

[151] *Louis Vitton*, 525 F. Supp. 2d at 569. *See also Wade-Greaux*, 874 F. Supp. 2d at 569 (excluding expert's testimony not because of inconsistency in lab notebooks, but because the inconsistency coupled with the limited amount of data "could affect substantially the statistical conclusions given the small number of rabbits used in the study by any measure.").

[152] Although Defendants make much of Dr. Saed reporting 48 hours in his initial manuscript, the error is irrelevant for two reasons: (1) the information was never published in *Gynecologic Oncology*; and (2) their claimed relation to observed mutations misconstrues the experiment and data.

[153] *See In re Paoli R.R. Yard PCB Litigation*, 35 F.3d at 744 ("This does not mean that plaintiffs have to prove their case twice—they do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are *correct*, they only have to demonstrate by a preponderance of evidence that their opinions are *reliable*.").

[154] *Daubert*, 509 U.S. at 595.

methods, not the correctness of their conclusions.[155] In other words, it is not the trial court's task to decide whether an expert's conclusions are *correct.*[156]

B. DATA FROM DR. SAED'S EXPERIMENT ARE VALID AND REPRESENT A PIECE OF THE BIOLOGIC PLAUSIBILITY PUZZLE

Defendants have continually argued that Dr. Saed's experiment is not reliable because it is an *in vitro* experiment that can't be extrapolated to establish human causation.[157] However, even the cases relied upon by Defendants support the proposition that Dr. Saed's experiment is useful and relevant. *In vitro* studies "can provide a reliable basis for medical and scientific opinions as long as there extrapolations are warranted."[158] As previously noted, *In vitro* tests "provide useful information about metabolic processes at a cellular level, and may supplement existing animal and human data."[159] *In vitro* studies or studies in cell culture may be conducted and are an important part of the totality of the evidence and the

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[155] *Daubert*, 509 U.S. at 585. *See also Beech Aircraft Corp. v. Rainey*, 488 153, 1969 (1988); Fed. R. Evid. 702.

[156] *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995) (*Daubert* II) ("[T]he *Daubert* test "is not the correctness of the expert's conclusion but the soundness of his methodology.").

[157] Defs. Mem. at 56 and citing *In re Human Tissue Prod. Liab. Litig.*, 582 F. Supp. 2d 644, 663 (D.N.J. 2008) for the proposition that *in vitro* studies are not as helpful as epidemiologic or animal studies.

[158] *In re Human Tissue*, 582 F. Supp. 2d at 663.

[159] *Bourne ex rel. Bourne*, 189 F. Supp. 2d at 496.

determination of general causation.[160] If results from both epidemiologic and toxicologic studies have been produced, "no universal rules exist for how to interpret or reconcile them."[161] However, both can be considered—"careful assessment of the methodological validity and power of the epidemiologic evidence must be undertaken, and the quality of the toxicologic studies and the questions of interspecies extrapolation and dose–response relationship must be considered."[162]

Dr. Saed's peer-reviewed published research stands on its own. In contrast to Defendants' arguments, Dr. Saed does not have to bridge the gap between the conclusions that he reached in his experiment and human causation. He does not have to do animal studies or replicate his results *in vivo* as Defendants proclaim.[163] Nor does a failure on his part to conduct animal studies implicate a failure to follow protocol, generally, or as it specifically relates to his experiment. More importantly, neither Dr. Saed's publication nor the opinions expressed in his expert report are based solely on the findings in his experiment. Instead, Dr. Saed relies upon conclusions he has reached in his experiment, other experiments that he has

[160] *Reference Manual on Scientific Evidence*, Fed. Judicial Ctr., 592 (3d ed. 2011) (hereinafter *Ref. Man.*) at 623, 674.

[161] *Id.* at 564.

[162] *Id.* at 564-565.

[163] Defs. Mem. at 57.

conducted, his professional experience and the body of literature related to talcum powder products to formulate his opinions.

Defendants cite to *Wessmann v. Gittens*, 160 F.3d 790 (1st Cir. 1998) to support their underlying premise that Dr. Saed is required to conduct animal. However, *Wessmann* is easily distinguishable from the present matter. In *Weissmann*, the court excluded testimony where the expert conceded that the data he used was not of the quality necessary to satisfy the methodological rigors required by his discipline.[164] In contrast, as a molecular biologist, the data obtained by Dr. Saed satisfies the methodological quality of his discipline and is thus reliable.

Defendants' arguments that Dr. Saed's data does not support his conclusions is not an appropriate basis for the exclusion of his opinions. The trial court is not empowered "to determine which of several competing scientific theories has the best province."[165] Instead, our inquiry focuses on principles and methodology and not on the conclusions they generate. The analysis of the conclusions themselves is for the trier of fact when the expert is subjected to cross-examination.[166] As long as the expert's testimony falls within "the range where experts may reasonably differ," then

[164] *See Wessmann*, 160 F.3d at 805.

[165] *Milward v. Acuity Specialty Prod. Grp., Inc.*, 639 F.3d 11, 15 (1st Cir. 2011) (internal quotation marks and citations omitted).

[166] *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 807 (3d Cir. 1997).

it is up to the jury to decide among the competing views.[167] Finally, the trial court does not have to focus on the conclusions the expert's methodologies create because that is a job for the jury.[168]

C. DEFENDANTS' ARGUMENT THAT THE PEER-REVIEW PROCESS SURROUNDING DR. SAED'S MANUSCRIPT WARRANTS EXCLUSION IS MISPLACED

[167] *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 153, 119 S. Ct. 1167, 143 L. Ed. 2d 238 (1999); *In re: Tylenol (Acetaminophen) Mktg., Sales Practices, & Prod. Liab. Litig.*, No. 2436, 2016 WL 4039286, at *2 (E.D. Pa. July 28, 2016) ("Fed. R. Evid. 702 and *Daubert* put their faith in an adversary system designed to expose flawed expertise."); *United States v. Mitchell*, 365 F.3d 215, 244–45 (3d Cir. 2004) (citations omitted) ("As long as an expert's scientific testimony rests upon 'good grounds, based on what is known,' it should be tested by the adversary process—competing expert testimony and active cross–examination—rather than excluded from jurors' scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies."); *In re Urethane Antitrust Litig.*, 166 F. Supp. 3d 501 (D.N.J. 2016) ("in serving the "gatekeeper function" and assessing the reliability of an expert's methodology, the Court must be mindful that in order to be admissible, a scientific method need not be the "best" method or one that is demonstrably correct. "Rather, the test is whether the 'particular opinion is based on valid reasoning and reliable methodology.')

[168] *See Kannankeril*, 128 F.3d at 807 ("Our inquiry focuses on principles and methodology and not on the conclusions they generate. The analysis of the conclusions themselves is for the trier of fact when the expert is subjected to cross-examination.") (citations omitted); *In re Actos (Pioglitazone) Prod. Liab. Litig.*, 2014 WL 60384, at *8 (W.D. La. Jan. 7, 2014) ("an expert can and does exercise his or her judgment and if he or she gives reasons for that decision and a full explanation for those choices, disagreement with those choice becomes a matter for the trier of fact.").

1. Dr. Saed's Conflict Disclosures Met All Necessary Disclosure Requirements

Faced with the reality that Dr. Saed has presented four abstracts based upon his research, his manuscript has been reviewed and accepted for publication in peer-reviewed journals, posters of the research have been presented at prestigious women's health conferences, and his research data has been reviewed for inclusion in a book chapter, Defendants feebly argue that Dr. Saed's opinions should be excluded because the peer-review process was irregular.[169] Defendants' argument is both factually and legally incorrect and should carry not weight.

As previously noted, Defendants' experts acknowledge that roughly two dozen independent professionals have looked at and reviewed Dr. Saed's research.[170] None of the researchers have questioned the nature of the funding or the impact that funding may have had on the results of Dr. Saed's work. Further, at no time did Dr. Saed "misrepresent" the nature of his funding as posited by Defendants. Instead, in each step of the various peer-review processes, Dr. Saed was transparent and provided the conflict information that was required. For example, in the manuscript submitted to Reproductive Sciences Dr. Saed disclosed that he "acted as a consultant

[169] Defs. Mem. at 75-79.

[170] *See* Birrer Dep. at 387:4-392:11 (Dr. Birrer acknowledging that 20 to 30 people have likely reviewed Dr. Saed's research).

regarding this topic for a fee."[171] As noted by Dr. Saed, that was sufficient language as required by the journal.[172] Where Dr. Saed was not required to disclose conflicts he did not do so.[173] When Dr. Saed was unsure of whether and how to disclose a conflict he inquired as to what the appropriate process would be.[174] It is because Dr. Saed abided by the various requirements when submitting his research for review that Defendants' dissatisfaction with the disclosures is of no affect.[175]

Defendants' arguments concerning Dr. Saed's financial interests are, at best, an attack on the weight of the evidence, not its admissibility. "Admissibility decisions focus on the expert's methods and reasoning; credibility decisions arise after admissibility has been determined."[176] Dr. Saed's research was subject to full

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[171] *See* Saed Publication at 12.

[172] *See* Saed Dep. at 142:12-18; 143:15-20; 145:2-18.

[173] *Id.* at 474:9-14; 477:1-5 (testifying that at time of submission of abstracts conflict disclosure was not required).

[174] *Id.* at 479:15-480:21; and Saed Dep. Exhibit 29 (testimony and e-mail exchange wherein Dr. Saed inquired as to whether specific financial disclosures had to be made).

[175] In the final version of the published manuscript the Declaration of Conflicting Interests stated: "The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this articles: Dr. Saed has served as a paid consultant and expert witness in the talcum powder litigation." *See* Saed Publication at 9.

[176] *Kannankeril*, 128 F.3d at 806. The cases cited by Defendants in support of their position are inapposite. In *Wade-Greaux*, 874 F. Supp. 1441, for example, although the court noted the expert's failure to disclose conflicts of interest, it was not the basis for excluding the expert's opinions. In *In re Garlock Sealing Techs., LLC*, 504 B.R. 71, 79 (Bankr. W.D.N.C. 2014), the court noted issue with that fact it was not

peer review and where, as required, contained the necessary disclosures of potential conflicts of interest. Dr. Saed is not new to publishing scientific literature as he has published over 130 scientific articles over the course of his career.[177] Dr. Saed has acknowledged that he did not state the "side" he consulted for but, based upon his experience with publishing a plethora of research papers, he did not deem it necessary. Furthermore, the language used in publication disclosures is typically chosen by the publisher/editors, and receives the same scrutiny as the article itself. In short, there is simply nothing improper or misleading about the disclosures provided by Dr. Saed.

2. The review of Dr. Saed's work by *Gynecologic Oncology* does not warrant exclusion

Defendants make much of the fact that Dr. Saed submitted his work to *Gynecologic Oncology* for consideration but it was not accepted. Based upon the comments of two reviewers Defendants argue that Dr. Saed's work was not accepted by ***relevant*** peers.[178] Defendants' argument makes no sense.

As previously noted, Dr. Saed's work has been reviewed by no fewer than twenty reviewers and editors. It has been the subject of four abstracts, published in

disclosed that materials used by the expert had been provided with funding by counsel, however, that was not the basis upon which the court excluded the opinions.

[177] *See* Saed Report at 3.

[178] *See* Defs. Mem. at 79 (emphasis in original).

a peer-reviewed medical journal, and presented at women's health conferences. Far from being irrelevant, the journal where Dr. Saed's manuscript was published, *Reproductive Sciences*, "publishes original research and reviews, editorials, and position papers in all aspects of reproductive biology and its translation to clinical medicine, including the disciplines of… ***gynecologic/reproductive tract oncology***."[179] In their attempts to argue that Dr. Saed's work should be excluded Defendants ignore that the reviewers from *Gynecologic Oncology*, reviewers the Defendants hold in such high regard, commented that "[o]verall this is a ***well written manuscript*** and the ***conclusions are supported by the results***."[180] The same reviewers also stated that "the authors compellingly show changes in several key enzymes regulating redox potential in cells exposed to talc."[181] Possibly the most significant comment was that "the significance of this study would be greatly enhanced if a mouse model corroborated the cell line findings"[182] The comment confirms that Dr. Saed's experiment did, in fact, have cell line findings to be corroborated.[183] Ironically, despite not knowing the identity of the two reviewers

[179] *See* **Exhibit D** (emphasis added).

[180] *See* **Exhibit M** (emphasis added).

[181] *Id.*

[182] *Id.*

[183] Defendants' experts confirmed the same. *See* Birrer Dep. at 341:12-17 ("Q. But the statement is 'The significance of this study would be greatly enhanced if a mouse

from *Gynecologic Oncology*, Defendants simply assume and argue that their comments must trump the comments of all others who have reviewed and approved of Dr. Saed's work. There is simply no basis for Defendants' position.

III. CONCLUSION

Dr. Saed has conducted original research relevant to the issues currently before this Court. The research has been peer-reviewed, published in multiple medical abstracts, and also published in a peer-reviewed medical journal. It has been reviewed and scrutinized by many independent editors and reviewers, none of whom identified methodological issues with his work. Dr. Saed's experiment and the scientific information he relies upon to support his opinions in the matter satisfy *Daubert* requirements. For the foregoing reasons Defendants' motion to exclude the expert opinions of Dr. Ghassan Saed should be denied.

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model corroborated the cell line findings.' So there were cell line findings to be corroborated; correct? A. Correct.").

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